



In the United States Patent Office

In re Application of

Karin Klokke, Kai-Thomas Kramer, Wilfried Fischer and Anna Sendl-Lang

Serial-No. 10/019 121

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Title: Matrix controlled transdermal system for stabile derivatives  
of ACE inhibitors

Declaration:

Joerg Nink declares:

That he is a citizen of Germany, employed by Hexal AG, Industriestrasse 25, D-83607 Holzkirchen, Germany;

and that he is a chemical engineer graduated at Darmstadt University  
and that he is senior scientist for TTS development at Hexal

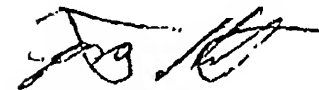
to which the application identified above has been assigned.

He checked the internal data base of Hexal, which confirms that the stability of 2  
ACE inhibitors contained in transdermale therapeutic systems has been tested by  
chromatographical analyses and further the flux of one of these inhibitors by means  
of a usual Franz cell. The following table presents the results.

ACE inhibitor	Purity at start	Purity after storage	Matrix components [%]	Permeation ( $\mu\text{g}/\text{cm}^2$ mouse skin/h) at start after storage
diester: Trandolaprilate di-ethylester	99.6%	99.5% 5 weeks 25°C >95%* 8 months 25°C	5 ACE inh. 95 silicone	about 3.4 about 3.4
monoester: Trandolapril per se	99%	57,3% 8 months 25°C	10 ACE inh. 90 polyacrylate	not measured

\*estimated

Joerg Nink further declares that all statements made herein of his own knowledge are true, and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that wilful false statements and the like, so made, are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the US Code, and that such wilful false statements may jeopardize the validity of the application or any patent issuing thereon.

  
Joerg Nink

29.05. 2007  
May 29, 2007